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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/091,665	09/02/98	ENDRIKAT J	SCH1637

HM12/0329

MILLEN WHITE ZELANO & BRANIGAN
ARLINGTON COURTHOUSE PLAZA I
2200 CLARENDON BOULEVARD
SUITE 1400
ARLINGTON VA 22201

EXAMINER	
QAZI,S	
ART UNIT	**PAPER NUMBER**
1616	8

DATE MAILED: 03/29/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/091,665	Endrikat et al.
Examiner	**Group Art Unit**
Sabiha Qazi	1616

☒ Responsive to communication(s) filed on *Jun 22, 1998* .

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-12* is/are pending in the application.

Of the above, claim(s) *9-12* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-8* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *9-12* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☒ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

First office Action on Merits

Invention: Instant invention is drawn to the contraceptive process and administering gestagen, estrogen and/or the combination thereof.

Status of the application

Claims 1-12 are pending.

Claims 1-8 are examined and rejected.

Claims 9-12 are withdrawn from consideration as non elected invention.

No claim is allowed.

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

I. Claims 1-8 are drawn to a contraceptive process, classified in class 514, subclass 182, 841, 843, 179.

II. Claims 9-12 are drawn to kits, classified in class 514, subclass 170, 182, 841, 843; class 424, subclass 464.

2. The inventions listed as Groups I and do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

3. Claims 1-8 are drawn to the contraceptive process by administering a combination of gestagen and natural estrogen. Claims 9-12 are drawn to kits which would require different searches. It would be a burden on the examiner to search the whole invention as claimed.

4. During a telephone conversation with Attorney Anthony Zelano on 2/29/2000 a provisional election was made with traverse to prosecute the invention of group I, claims 1-8. Affirmation of this election must be made by applicant in replying to this Office action. Claims 9-12 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventor ship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventor ship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Gast and Koninckx (US Patent 5,747,480 and US 5,827,843). See lines 5-67, col. 2, examples 1-7, col. 3 and 4; claims 1-9. Of '843; lines 8-67, col. 7; lines 26-67, col. 8; lines 1-30, col. 9, examples 1 and 2, cols 9 and 10; claims 1-26.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neuman, Friedmund (CA 118:161077, abstract of Pharm. Ztg. (1992), 137(34), 9-15). Neuman teaches the application of estrogen-progestagen drug combination in gynecology, both for contraception and for the treatment of various disorders and their mechanism of action the application forms and side effects are also described. (See abstract).

Instant invention is drawn to the process of contraceptive by administering gestagen, estrogen and/or the combination thereof.

It would have been obvious to one skilled in the art at the time of invention to use gestagen, estrogen or the combination of both for the contraceptive process as instantly claimed particularly when prior art teaches the combination of gestagen

and estrogen for the same purpose. There has been ample motivation provided by the prior art to prepare the instant invention.

The determination to employ the optimum proportion of the ingredients as cited in claims would have been within the skills of the one familiar with the art. These numerical limitations of the molar ratios recited in claims of the instant invention do not distinguish the claims over the prior art because they would have been obvious to one skilled in the art in the absence of a showing of criticality, of unobviousness or unexpected results over the prior art.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill might reasonably infer from the teachings. *In re opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA 1976). A reference is not limited to working examples. *In re Fracalossi* 215 USPQ 569 (CCPA 1982).

Accordingly, the burden of proof is upon applicants to show that instantly claimed subject matter is different and unobvious over those taught by prior art. See *In re Brown*, 173 USPQ 685,

688; *In re Best*, 195 USPQ 430 and *In re Marosi*, 218 USPQ 289, 293.

In the light of the forgoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a).

The data showing any unexpected results would overcome the above 35 U.S.C. 103(a) rejection.

2. Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gast and Koninckx (US Patent 5,747,480 and US 5,827,843). See lines 5-67, col. 2, examples 1-7, col. 3 and 4; claims 1-9. Of '843; lines 8-67, col. 7; lines 26-67, col. 8; lines 1-30, col. 9, examples 1 and 2, cols 9 and 10; claims 1-26. All the references cited above teach the oral contraceptive process and use of combination of gestagen and estradiol.

Instant invention is drawn to the process of contraceptive by administering gestagen, estrogen and/or the combination thereof.

Instant claims differ from the reference in claiming different sequential and duration.

It would have been obvious to one skilled in the art at the time of invention to use gestagen, estrogen or the combination of both for the contraceptive process as instantly claimed particularly when prior art teaches the combination of gestagen and estrogen for the same purpose. There has been ample motivation provided by the prior art to prepare the instant invention.

The determination to employ the optimum proportion or combination of the ingredients as cited in claims would have been within the skills of the one familiar with the art. These numerical limitations of the molar ratios recited in claims of the instant invention do not distinguish the claims over the prior art because they would have been obvious to one skilled in the art in the absence of a showing of criticality, of unobviousness or unexpected results over the prior art.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill might reasonably infer from the teachings. *In re opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA 1976). A reference is not limited to working examples. *In re Fracalossi* 215 USPQ 569 (CCPA 1982).

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In the light of the forgoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a).

The data showing any unexpected results would overcome the above 35 U.S.C. 103(a) rejection.

References in the form 892 are cited to show the state of prior art.

Minor Informalities

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

The references in the form 892 are cited to show the state of prior art.

Telephone Inquiry Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha N. Qazi, whose telephone number is (703) 305-3910. The examiner can normally be reached on Monday through Friday from 8 a.m. to 6 p.m. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

Sabiha N. Qazi Ph.D.

Examiner,

Art Unit 1616

3/25/2000